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EXAMINER

PATEL, SUDHAKER B

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/541,795

Applicant(s)

LINK ET AL.

Examiner

Sudhaker B. Patel, D.Sc.Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 and 45-60 is/are pending in the application.
- 4a) Of the above claim(s) 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 26-36 and 38-43 is/are rejected.
- 7) ☒ Claim(s) 20-25, 37 and 45-60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicants' communication paper # 21 dated 7/10/03 is acknowledged.

1. Upon further review and reconsideration this application is found not ready for the allowance at this stage for the reasons stated below.

The method of use claims and the intermediate related claims 20-25,44-60 are withdrawn from consideration. Applicants have cancelled claim 44. Examiner has considered claims 1-19, 26-43 related to compounds and compositions only.

Therefore, the claims under consideration are the claims 1-19,26-43.

Because the compounds and their compositions claims are not yet allowed for the reasons stated below, the method of use claims can not be considered for allowance prior to the compounds by the examiner.

Inconvenience caused to applicants by recitation of method of use claims in earlier communication dated 4/11/03, is regretted.

- Examiner has searched the compounds in the following way:
- The initial search for the species of Example 399 as recited on page 349 did not reveal any art.
- The search was expanded to meaning of AR = Aryl/Phenyl. Prior art ref. Franke et al(Helve. Chimica Acta, 58/1,268-78(1975), also cited as Chemical Abstract DN 82:124989, see compound with CAS RN # 54875-53-5) was found. Applicants have excluded the compounds of Franke by proviso(s).
- The search was further expanded to genus of Formula of claim 1. No art was found.

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The method of use claims are not searched by Examiner because the same will involve additional search time for a through examination, which is time consuming and burdensome.

The restriction/election is considered proper and is now made FINAL.

Double Patenting

2. Rejections maintained:

Applicants' arguments and remarks for withdrawal of DP rejections (U.S. P. 6110922) made in earlier Office Action paper # 18 dated 4/11/03 are maintained further. This is because applicants have not surrendered the patent rights as per the record.

3. Rejections maintained:

Applicants' arguments and remarks for withdrawal of DP rejections (U.S. Application Sr. # 09695040 filed 10/24/2000) made in earlier Office Action paper # 18 dated 4/11/03 are maintained further. This is because applicants want the disclosure for allowable subject matter first.

Examiner's position:

Applicants' compound claims are conflicting with above and bellow stated cases, and therefore, continuation of the rejections made earlier, further, it is not possible for the office to go for the allowance without applicants resolving the pending issues stated herein.

Priority

4. The priority for the U.S. Application Sr. NO. 09541795 filed 3/31/2000 will be the date of filing this application for the reasons stated bellow.

New Rejections:

Double Patenting

5. Claims 1, 19,20-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 21,22,23,26,28, related to compounds of Formula I, claim 15 related to composition, and claims 16-19 related to method of use of copending Application No. 10356794, filed 8/29/2002. Although the conflicting claims are not identical, they are not patentably distinct from each other because The Formula I has a core: Ar-S-Phenyl having substituents R1-R5 for which the instant meanings are overlapping. The composition claim 15 and method of use claims 16-19 are also reciting the same generic disease e.g. " A method of inhibiting inflammation"; " A method of suppressing immune response".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

As applicants are aware the prosecution for the U. S. Application Sr. # 10356794 has not been closed, and therefore, it is not possible for the examiner to go for the allowance of the instant application at this stage.

New Rejections:

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,19,20-23,26-36,37-43,45-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Link et al(U.S.P.6110922)

The applied reference has a common inventor(s) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

The US patent applied as of its filing date and has a different inventive entity than herein. It discloses many compounds within the instant scope for uses urged treatable on by inhibition of inflammation and by suppressing immune response.

It is recognized that applicants are urging benefit of U.S. Application Sr. # 09474517 filed 12/29/1999 under 35 U.S.C. 120 and under 35 U.S.C. 119. However, to obtain such benefit, claims must comply with 35 U.S.C. 112, paragraph one, namely

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description and enablement as was set forth in *In re Scheiber* 199 USPQ 782; *In re Chu* 36 USPQ2d 1089.

Currently only the instant filing date is accorded the claims since subject matter claimed herein is not entirely described in the earlier parent, US ' 517 Compare values of Ar-S-Phenyl having different meanings for the substituents in the following manner:

- The definitions for R1 to R5 has i. ,9= heterocyclylsulfany) which is not present in the parent ' 517;
- The definitions for R10 and R11 has f., l., m., n., o. which are not present in the parent '517;
- The definition of component –NR10 T11 is defined with a different scope in the instant claims 1,10;
- The definition(s) for substituents onto R10 and R11 when forming a ring has 37)-46) meanings which are not present in the parent '517;
- The definitions of instant substituents to Ar group has x., y.,z., aa.,gg.,hh.,ii., which are not present in the parent '517.
- The claims 24-60 in the instant application are not present in the parent '517 which do not support the scope of the same.
- Additionally the species of claims 12-13 are also not entirely described in

the earlier patent of which present case is CIP.

7. Rejections withdrawn:

Applicants' arguments and remarks have been considered, and found persuasive. Therefore, rejections made under 35 U.S.112, paragraph second are now withdrawn.

8. New Rejection:

Claims 1-19, 26-43 recite : " heterocyclyl, heterocyclylalky etc.l" for variables e.g. R10,R11, Ar. This is indefinite because the applicants do not exactly state which heteroatoms are present in these rings, how many of each are present in these rings, what SIZE RINGS ARE INTENDED AND HOW MANY RINGS ARE PRESENT.

Claims 2-19,26,29-33,39,43 are cited as rejected because they are dependent on rejected claim(s).

Applicants are reminded that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see e.g. In re Van Guens, 988 F. 2d 1181, 26 PSPG 2d 1057 (Ded. Cir. 1991). Accordingly, without the recitation of all these critical limitations, the claims do not adequately define the instant invention.

Claims 37,40, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite:" comprising" for describing compound(s). Corrections with consisting are required.

Claim Objections

9. Method of use claims and claims related to intermediates, namely claims 20-25,45-60 objected because applicants have not cancelled same. They are the non-elected claims.

Independent compound claim 37 is also objected because it does not exactly and definitely describe the invention. "Diarylcinnamide compound" does not say exactly about the structures of the compounds because AR as recited by the applicants can be both phenyl/aryl as well as heteroaryl. See rejections above.

Conclusion

Allowable Subject Matter

10. The following is a statement of reasons for the indication of allowable subject matter:

11. Claims 1-19, 26-43 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and resolving of the various other issues as recited earlier, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. Applicants have deleted the prior art ref. Franke et al (Helve. Chimica Acta, 58/1,268-78(1975), also cited as Chemical Abstract DN 82:124989, see compound with CAS RN # 54875-53-5).

13. The other art reference Alain Platel et al (U.S.P. 4808582) teaches making of Cinnamoic compounds which are useful as drugs having stimulating, protecting, and correcting activities of the cerebral functions.

14. The references either alone or in combination do not suggest or teach to arrive at the instant compounds.

15. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is 703 308 4709. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on 703 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.


Sudhaker B. Patel, D.Sc.Tech.
August 25, 2003.


MUKUND SHAH
SUPERVISORY PATENT
EXAMINER
ART UNIT 1624